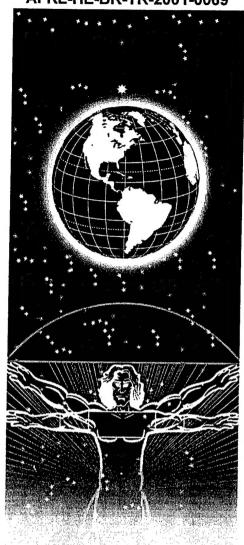
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UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE SOS, Ltd., HYPERLITE, EMERGENCY EVACUATION HYPERBARIC STRETCHER, MODEL 24/88/SAT/70

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November 2000

Approved for public release; distribution unlimited.

NOTICES

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TESTING AND EVALUATION OF THE SOS, Ltd., HYPERLITE, EMERGENCY EVACUATION HYPERBARIC STRETCHER, MODEL 24/88/SAT/70

BACKGROUND

Air Force Medical Equipment Development (AFMED) was approached by members of the 311 HSW School of Aerospace Medicine, Davis Hyperbaric Laboratory to participate in evaluating and approving the SOS, Ltd., Hyperlite, Emergency Evacuation Hyperbaric Stretcher (EEHS), Model 24/88/SAT/70 for use on board USAF aeromedical evacuation aircraft. This venture was in response to fulfill a need generated by a Foreign Comparative Testing Program initiated by the U.S. Navy to find an inexpensive, portable means to perform hyperbaric treatments both on the ground and in the air.

Specific components that underwent the evaluation process were the SOS, Ltd., Hyperlite, Emergency Evacuation Hyperbaric Stretcher, Model 24/88/SAT/70 basic unit (S/N: 0000008994); the Control Box Model Z08 (S/N: 005); Mine Safety Appliances, Co., Model 3000 Oxygen Monitor; David-Clark, Inc., Wired Headset System, Model 200 modified with kit # WRC-HYBICS; the SOS, Ltd., Hyperlite, Internal Stretcher; Apeks gas regulator (P/N: 0098 EN250, SN: 970992); Amron International Diving Supply Inc., SCOTT® Pressur-Vak II Inhalator with Overboard Discharge, Series 803139-00 (P/N: 803152-02); Catalina S-80 (steel/80 cubic feet of air) dive tanks, DOT number 3AL3000AS194479M4002 02A99 S80; and patient comfort pad. All components of the EEHS were tested for airworthiness. Throughout this report, the term Equipment Under Test (EUT) refers to the EEHS and all internal and external components as a unit.

DESCRIPTION

The EUT is a portable and collapsible hyperbaric chamber that can be used as a means of transporting personnel suffering from decompression sickness, gas embolism, or other approved maladies to a definitive treatment facility. The EUT provides an easily transported means of emergency evacuation of a casualty, while under pressure, from the diving incident site to a land-based hospital facility. The EUT is a deployable unit and is designed for manual transport while pressurized (compressed air) with one occupant. The EUT incorporates a means of observing and administering oxygen to the occupant while pressurized.

The EUT comes equipped with a flexible pressure chamber, which can withstand maximum working pressures up to 69 feet seawater or 30.5 pounds per square inch. The EUT has two full diameter, self-sealing acrylic end domes. Once the end domes are inserted into the ends of the pressure chamber and pressure is applied the end domes push outward against the pressure chamber creating a seal. The end domes also provide access via a medication port located at the head end and access ports for communications, patient monitoring, oxygen administration and monitoring, and a means to pressurize the pressure chamber. The Hyperlite Control Box has a manifold to distribute oxygen to the patient and compressed air to the pressure chamber. The Hyperlite control box is also equipped with two gauges to monitor system pressure for air and oxygen. There is also an internal depth gauge indicator. Mine Safety Appliances, Co., Model 3000 Oxygen Monitor diplays oxygen concentrations inside the pressure chamber. The Built In Breathing System (BIBS) consists of an Amron International Diving Supply Inc.,

SCOTT® Divers Inhalator Mask, Pressur-Vak II series, Model 803139. The Pressur-Vak II is designed to deliver pressurized breathing gases to a patient in a hyperbaric environment. It eliminates oxygen and carbon dioxide build up by dumping exhaled gases directly out of the chamber. A David-Clark, Inc., Wired Headset System model 200, modified with Kit # WRC-HYBICS is used for communication between the patient inside the pressure chamber and support personnel outside the pressure chamber. Throughout testing, the EUT operated off one or more S-80 (steel/80 cubic feet of air) compressed gas cylinders manufactured by Catalina. The EUT manufacturer also provided a patient comfort pad. The dimensions of the pad are 68" length X 8.5" wide X 1.25" thick. The EUT weighs approximately 123 lbs. Its dimensions are length 88 in. with a diameter of 23.5 in. Internal pressure chamber volume is 18 cubic feet. The dimensions of the transport cases are approximately 29" wide X by 25" deep X 29" high (large) and 26" wide X 15" deep X 26" high. The complete EUT with all components to include storage containers, dive tanks, etc. weighs approximately 300 lbs.

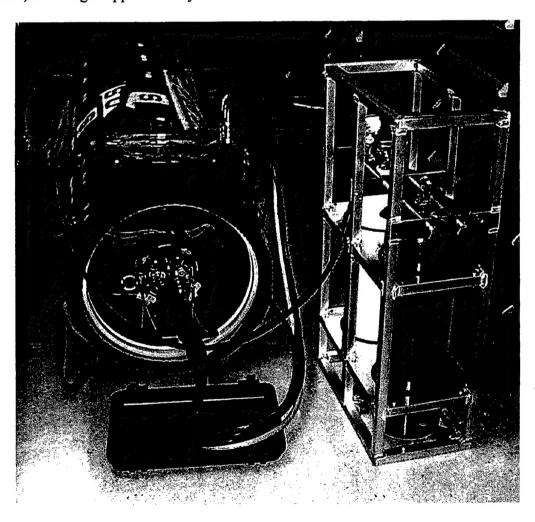


Figure 1. SOS, Ltd., Hyperlite, Emergency Evacuation Hyperbaric Stretcher, Model 24/88/SAT/70

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1, 2), military standards (3, 4, 5), and manufacturer's literature (6, 9, 10). The AFMED Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (7). A test setup and performance check was developed specific to this EUT to verify its proper functioning under various testing conditions. All tests were conducted by AFMED personnel assigned to the Protective Systems Branch, Biodynamics and Protective Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas unless otherwise noted. An Air Transportability Certification Letter and aircraft tie-down procedure was released by the Aeronautical Systems Center at Wright-Patterson AFB approving the EUT for air transport and operation with patient on the C-5, C-9, C-130, C-141, C-17, and KC-135 aircraft (see Appendix "C").

The EUT was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

- 1. Initial Inspection and Test Preparation
- 2. Vibration
- 3. Electromagnetic Interference (EMI)
- 4. Thermal/Humidity Environmental Conditions, encompassing:
 - a. Hot Operation
 - b. Cold Operation
 - c. Humidity Operation
 - d. Hot Temperature Storage
 - e. Cold Temperature Storage
- 5. Hypobaric Conditions
 - a. Cabin Pressure/Altitude
 - b. Rapid Decompression to simulated flight level
- 6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

- a. The EUT was inspected for quality of workmanship, production techniques and preexisting damage.
- b. The EUT was examined to ensure it met basic requirements for human factor design as outlined in MIL-STD 1472 F (3).
- c. A test setup and performance check was developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

Test Setup: The six (6) individual devices/subsystems that compose the EUT were evaluated separately. They are: The EEHS, Mine Safety Appliances, Model 3000 Oxygen Monitor; the Built In Breathing Device (BIBS) that consists of a SCOTT® Pressur-Vak II Inhalator with Overboard Discharge; David-Clark, Inc., Wired Headset System model 200, modified with Kit # WRC-HYBICS, Catalina dive tanks, and dive tank storage rack. Individual device/system descriptions and performance checks are outlined below.

The Hyperlite pressure chamber and end domes provide a pressurized environment needed to adequately treat decompression sickness or air gas embolism symptoms. The pressure chamber with end domes inserted is filled to the appropriate treatment depth using compressed air. Individual hose connections to penetration plate and control box are unique preventing cross contamination or confusion at set up. Pressure is controlled and maintained by an external control box. To monitor internal chamber pressure, an internal depth gauge is mounted on the inside of the foot-end dome.

Performance Check: A performance check was used to validate the function of the Hyperlite pressure chamber, end domes with internal depth gauge, and control box during vibration, altitude, rapid decompression and environmental testing. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The Hyperlite pressure chamber, end domes with internal depth gauge; and control box performance check is defined below.

Procedure:

- 1. Configure Hyperlite to manufacturer's directions.
- 2. Connect appropriate hoses from Hyperlite end dome to control box.
- 3. Connect Tank and Regulator to control box.
- 4. Connect fill hose with muffler attached to interior portion of end dome.
- 5. Insert an end dome into each pressure chamber opening. Apply outward pulling-pressure on end domes to ensure seal.
- 6. Pressurize compressed air line and fill Hyperlite to 60 FSW. NOTE: Ensure system

pressure is maintained at 60 FSW.

7. Measure and record system pressure (control box gauge).

The Mine Safety Appliances, Co., Model 3000 Oxygen Monitor (previously approved for USAF aircraft use) provides oxygen monitoring capability inside the pressure chamber. A complete evaluation report of the Mine Safety Appliances, Co., Model 3000 Oxygen Monitor can be found in published technical report # AFRL-HE-BR-TR-1998-0120.

The Built In Breathing System (BIBS) consists of an Amron International Diving Supply Inc., SCOTT® Divers Inhalator Mask, Pressur-Vak II series and provides a means of supplying oxygen therapy to the transported patient.

Performance Check: A performance check was used to validate the function of the BIBS during dive and environmental testing. Operation of BIBS was in accordance with SCOTT® Aviation, Inc., Operating and Maintenance Instructions (9). System checks accomplished during initial operation at standard ambient conditions served as a baseline for later comparison. The BIBS performance check is defined below:

- Connect BIBS oxygen and exhalation lines to appropriate ports on interior side of end dome.
- 2. Connect oxygen line to gas source and Hyperlite control box.
- 3. Charge oxygen line.
- 4. Check control box oxygen pressure gauge to ensure adequate pressure is maintained.
- 5. Place breathing mask over face and breathe into the mask to ensure no restrictions in normal breathing process.

The David-Clark, Inc., Wired Headset System, Model 200 modified with kit # WRC-HYBICS, provides communication between the patient and outside observer. The system uses communication ports penetrating through an EEHS foot-end dome. The Wired Headset System is "hot miked" and consists of two headsets, one with a boom mike and the other with a throat mike. It is powered by one 9 VDC transistor battery. An additional backup battery is located in the communication box and can be activated by using the toggle switch on the outside of the communication box.

The Wired Headset System is composed of four main components: patient headset, connecting cable from chamber to the intercom master, intercom box, and an operator headset. The components for intercom kit # WRC-HYBICS modified by David-Clark Inc., are listed below:

- 40468G-01 Headset with throat mike modified for use with the system
- 18253G-01 Adapter Cord assembly modified for use with the system
- DC-Com-200 Aviation intercom master modified to meet the requirements of the hyperbaric system
- H10-123.4 Aviation Headset

Performance Check: A performance check was used to validate the function of the David-Clark, Inc., Wired Headset System, Model 200 modified with kit # WRC-HYBICS, during EMI and environmental testing (10). System checks were accomplished during initial operation at standard ambient conditions and served as a baseline for later comparison. The David-Clark, Inc., wired headset system, performance check is defined below.

- 1. Connect the patient headset with throat mike to the interior LEMO® connector communication port on the end dome.
- 2. Connect the exterior communication wire to the exterior LEMO® communication port on the end dome.
- 3. Connect the other end of the exterior communication wire to the David-Clark control box.
- 4. Connect the outside observer headset to the David-Clark control box.
- 5. Turn on the David-Clark control box.
- 6. Place headsets onto AFMED personnel to assess sound and voice quality.

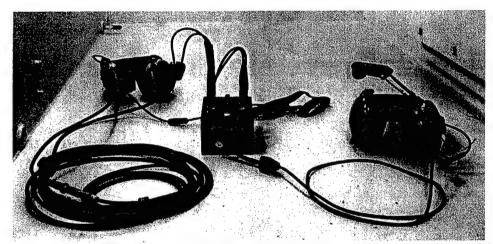


Figure 2. David-Clark, Inc., Wired Headset System model 200, modified with Kit # WRC-HYBICS

The Catalina S-80 (steel/80 cubic feet of air) dive tanks were used to provide compressed air to the EUT. The dive tanks were inspected and filled by a certified diving facility prior to testing of the EUT.

Performance Check: The following performance check was used to validate the function of the Catalina S-80 dive tank during dive and vibrational testing The dive tank performance check is defined below:

- 1. Have tanks professionally inspected and serviced by certified personnel.
- 2. Connect regulator to dive tank.
- 3. Open valve to pressurize system.
- 4. Record pressure and observe for leakage.

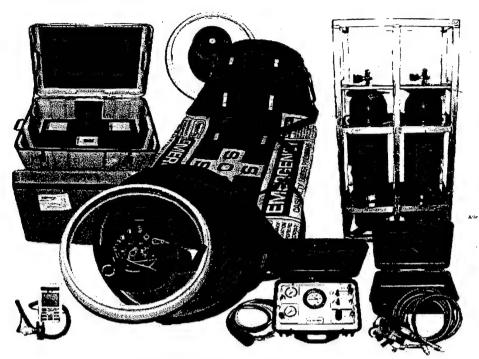


Figure 3. System Components

PERFORMANCE CHECK

The above individual performance checks were used to validate the function of the Hyperlite system and subsequent devices in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the Hyperlite system and subsequent devices is as defined above and will be referenced throughout the Test Condition section.

VIBRATION

Vibration testing is critical to determine, the resistance of equipment to vibrational stresses expected in its shipment and application environments. Testing was conducted on an Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30, and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT was secured to the vibration table using three 5,000 lbs., cargo tie-down straps, and six "D" rings. The EUT was subjected to vibration curves (figures 6-10) with similar intensities and durations as those derived from MIL-STD 810F, Category 10, Figures 514.4-16 and 514.4-17

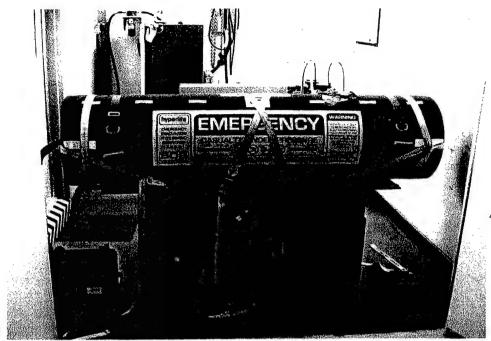


Figure 4. Vibration Table Mounting

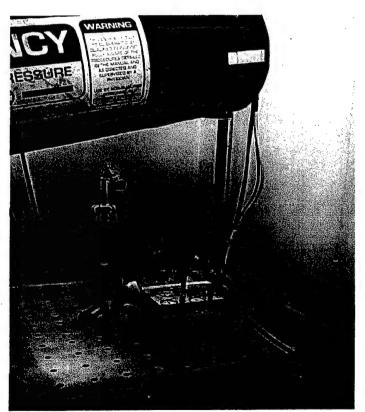
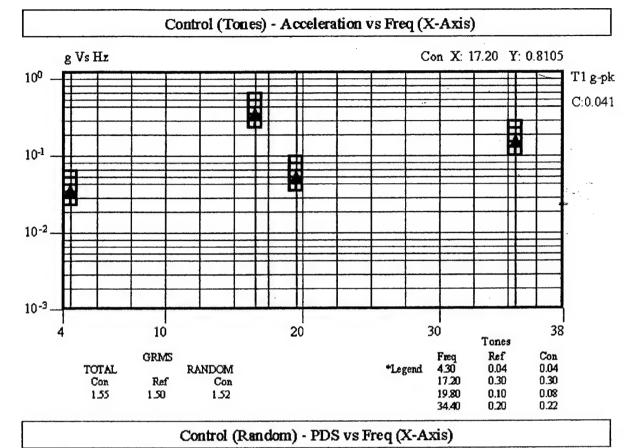


Figure 5. Vibration Table Mounting



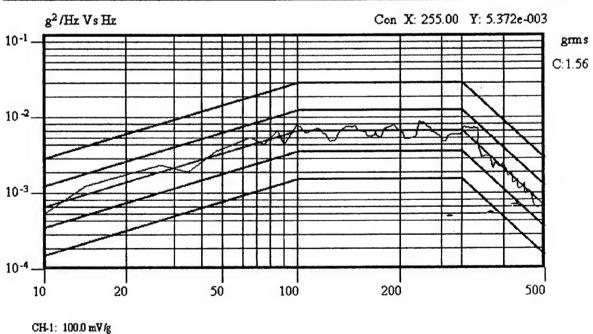


Figure 6. Helicopter (Sine-On-Random) X-Axis based on MIL-STD 810F

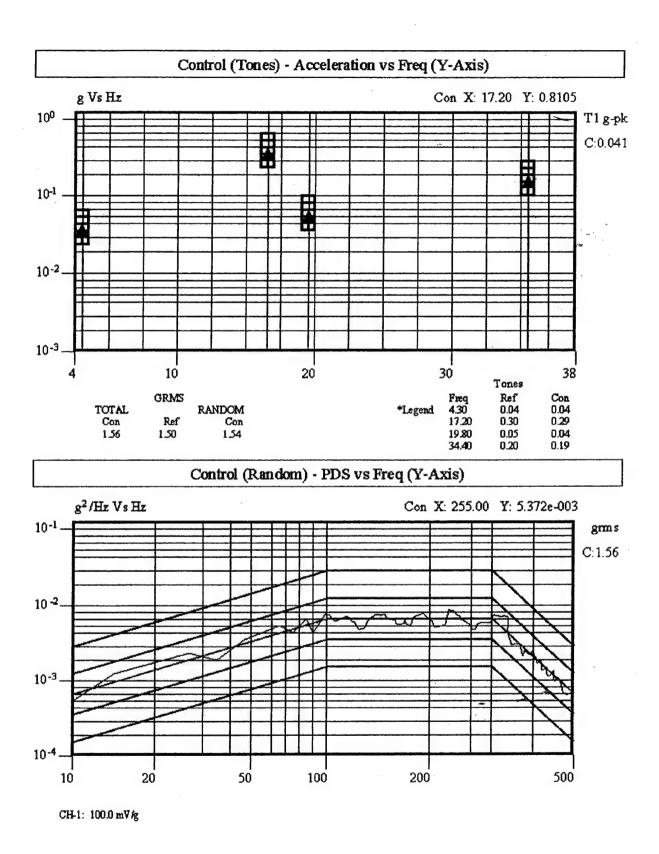
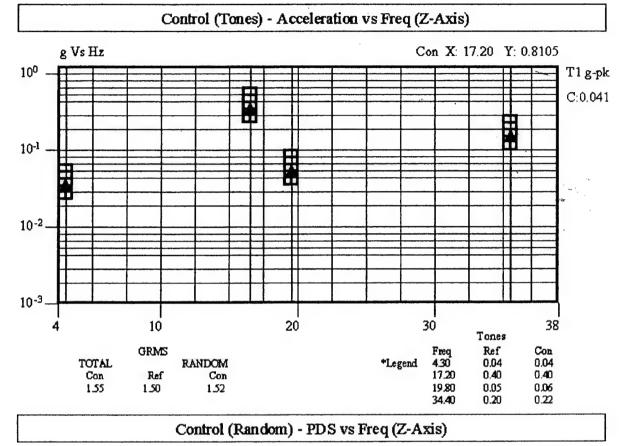


Figure 7. Helicopter (Sine-On-Random) Y-Axis based on MIL-STD 810F



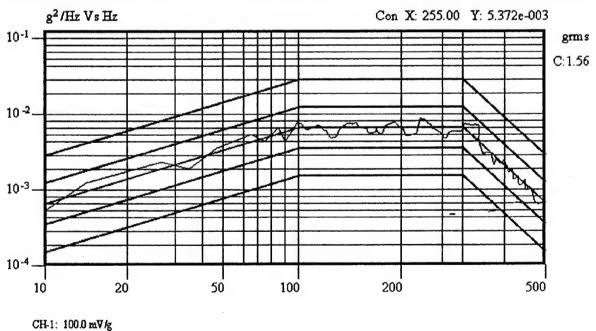


Figure 8. Helicopter (Sine-On-Random) Z-Axis based on MIL-STD 810F

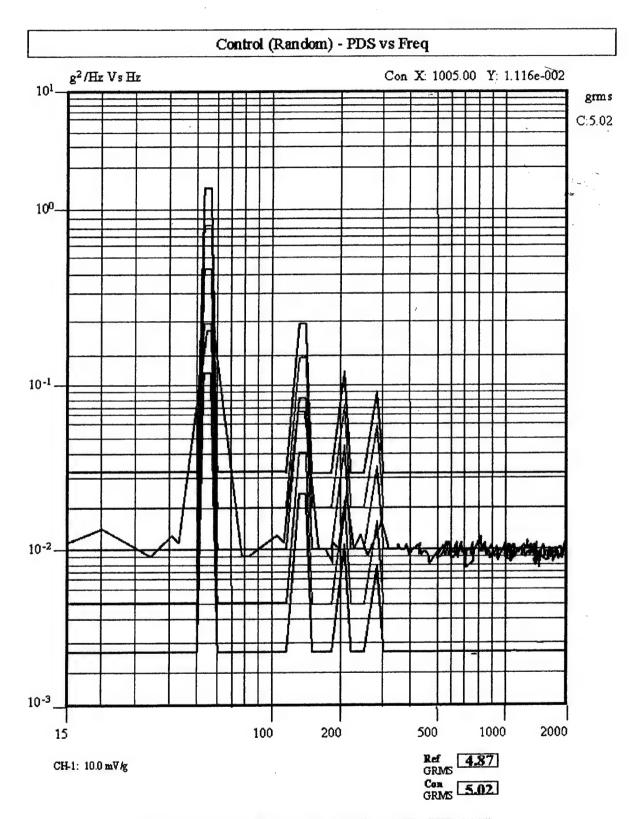


Figure 9. C-130 Turbo-prop based on MIL-STD 810F

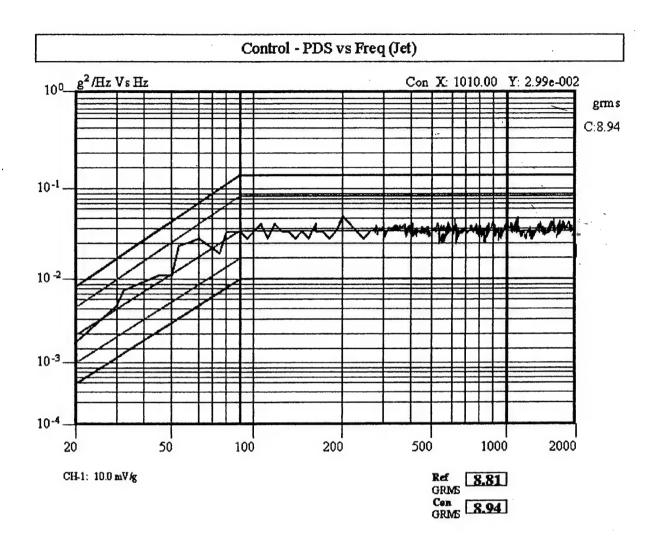


Figure 10. Jet Random based on MIL-STD 810F

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility is a primary concern for equipment to be used safely on USAF aeromedical evacuation aircraft. Emissions from medical equipment may cause electromagnetic interference (EMI) with potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment resulting in malfunction and/or patient safety issues. Only those components of the EUT that were electronic (battery operated) were subjected to EMI tests. This consisted of the communication system and internal sensor. All other components were mechanical and not subject to influence of EMI.

The David-Clark, Inc., Wired Headset System, Model 200 modified with kit # WRC-HYBICS wired headset system was evaluated for compliance with MIL-STD 461E (5). ASC/ENAE engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

- a. Radiated Emission (RE-101), Radiated Emissions, Magnetic Field, (30 Hz to 100 Hz) This requirement is specialized and is intended primarily to control magnetic fields for applications where equipment is present in the installation, which is potentially sensitive to magnetic induction at lower frequencies.
- b. Radiated Emissions (RE-102), Radiated Emissions, Electric Field, 10 kHz to 18 GHz.: The requirements are applicable to electric field emissions from the EUT and associated cables. The basic intent of the requirement is to protect sensitive receivers from interference coupled through the antennas associated with the receiver. This test measured the amount of EMI emitted by the EUT during operation. It verifies the EUT's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).
- c. Radiated Susceptibility (RS-101), Radiated Susceptibility, magnetic fields, 30 Hz to 100 kHz. This requirement is specialized and intended primarily to ensure that performance of equipment potentially sensitive to low frequency magnetic fields is not degraded.
- d. Conducted Susceptibility (CS-114), Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz. For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether or not simulated currents developed on platform cabling, from electromagnetic fields generated by antenna transmission, would affect the equipment under test.
- e. Conducted Susceptibility (CS-115), Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation: This test was performed to ensure the EUT could withstand the fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse.

f. Conducted Susceptibility (CS-116), Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power Leads, 10 kHz - 100 MHz, respectively. The basic concept of this test is to simulate electrical current and voltage waveforms occurring in platforms from excitation of natural resonances.

During emissions testing, all the electrical components/devices were operating for the duration of the tests. For both emissions and susceptibility testing, the Wired Headset System was tested for operation using internal battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance. Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions; overheating; changes in lubricant viscosity; corrosion; changes in electronic components; and electronic/mechanical failures due to rapid water or frost formation.

Due to the EUT's size and footprint, testing was conducted in a large calibrated environmental chamber belonging to the Air Force Research Laboratory, Research Chambers Operation. The EUT was placed in the center of the environmental chamber. For operational tests, the EUT was monitored continuously and a performance check was conducted every 15 minutes. For storage tests, the EUT was placed in the chamber and remained non-operational throughout the storage portion of the test. Additional manned tests were performed during cold temperature and hot operation to mainly evaluate the performance of the SCOTT® Pressur-Vak II mask. The following describes the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}F \pm 3.6^{\circ}F$ ($29.5^{\circ}C \pm 2^{\circ}C$) for 4 hr
- b. Hot Temp Operation: $104^{\circ}F \pm 3.6^{\circ}F$ ($40^{\circ}C \pm 2^{\circ}C$) for 2 hr
- c. Cold Temp Operation: $32^{\circ}F \pm 7.2^{\circ}F$ ($0^{\circ}C \pm 4^{\circ}C$) for 2 hr
- d. Hot Temp Storage: $140^{\circ}F \pm 3.6^{\circ}F$ ($60^{\circ}C \pm 2^{\circ}C$) for 6 hr
- e. Cold Temp Storage: $-40^{\circ}F \pm 3.6^{\circ}F$ ($-40^{\circ}C \pm 2^{\circ}C$) for 6 hr

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on operation of the equipment. Majority of aircraft, characterized as opportune aircraft, available for use in aeromedical evacuation maintain cabin pressures equivalent to 8,000 - 15,000 ft above sea level. Altitude testing consisted of operating the EUT while ascending from ground level to 15,000 ft, stopping at 2,000

ft increments for performance checks. The rates of ascent and descent were 5,000 ft/min. Testing was conducted in a calibrated man-rated altitude chamber belonging to the Air Force Research Laboratory, Research Chambers Operation.

Rapid Decompression (RD) Testing: A rapid decompression is the sudden loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressure. It is important to assess medical equipment functioning during and after RD so as not to endanger patients, personnel, or the aircraft. The EUT operated inside the rapid decompression test chamber as the chamber was depressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for approximately five minutes, and then returned to ground at a rate of 10,000 - 12,000 ft/min. The test was repeated twice more, once for a 7-second RD and once for a 1-second RD. The EUT was now monitored throughout the series of decompressions. Performance checks were assessed each time the EUT returned to ground level. Testing was conducted in a calibrated man-rated altitude/rapid decompression chamber belonging to the Air Force Research Laboratory, Research Chambers Operation.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability of medical equipment items under actual operating conditions. In-flight test and analysis demonstrates the EUT's ability to provide patient care on board USAF aircraft. Safe and reliable operation is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

EXPLOSIVE ATMOSPHERE

Testing is performed at the WRACC/TIECD (Engineering Test Facility) Robins AFB, Georgia. This test is conducted to assess the unit's safety while operating in a fuel-enriched and reduced hypobaric environment under simulated flight conditions. Testing is conducted based on guidance found in MIL-STD 810F, Method 511.4. A test report is generated at the end of testing and results were forwarded to AFMED for inclusion in technical reports. This test is required by Headquarters Air Mobility Command (SGXW) for electronic medical devices proposed for use onboard USAF tanker aircraft.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed separation of the blue, outer covering of the pressure chamber, particularly around the outer edges. AFMED determined these separations were in non-critical

areas and did not degrade pressure chamber function. AFMED determined the cause to be excessive movement during shipping and notified the manufacturer. A detailed inspection proved the manufacturing process of the pressure chamber was adding additional, unneeded material to the outer edge causing excessive friction and shear forces on the pressure chamber edge. The manufacturer modified the production process to prevent premature edge separation during shipping. The Hyperlite system check performed to the manufacturer's specification.

During initial evaluation, AFMED found the Hyperlite Internal Stretcher, to be of poor quality. The material used to support the patient's weight was inferior and could not support a patient weighing approximately 220 lbs. It was noted after weight was applied to the patient stretcher the fabric separated in two or more places along the internal stretcher frame. In addition, the stretcher frame itself separated during the unloading process making it difficult to fully extricate the simulated patient from the pressure chamber. The US Navy Experimental Dive Unit abandoned its evaluation of the stretcher.

In the interest of safety, it was noted one additional encircling strap with two carrying handles should be added to the outside of the Hyperlite patient chamber at its mid-point. As recommended in MIL-STD 1472F, section 5.9, the amount of weight lifting and proper technique should be followed so that risk of injury is minimized during EUT manual carrying.

VIBRATION

The EUT was secured to the vibration table using cargo tie-down straps with the straps running over and around the pressure chamber (see g. under Summary). The EUT performed according to manufacturer's specifications and AFMED guidelines without any system failure or malfunction.

The David Clark, Inc., Wired Headset System, Model 200 modified with kit # WRC-HYBICS was not evaluated for vibration. This device was deemed hand-held and will be carried by the outside operator on a belt clip or belly pack.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAE, Wright-Patterson AFB IAW Air Force Instruction 11-202, Volume 3, Flight Safety, certified the David-Clark, Inc., Wired Headset System modified with kit # WRC-HYBICS, for use in the aeromedical evacuation system on all U.S. Air Force aircraft (including small and large body, fixed and rotary wing) while operating from internal battery power. The David-Clark, Inc., Wired Headset System, Model 200 modified with kit # WRC-HYBICS wired headset system failed to meet the Army CS-114 conducted susceptibility requirements for MIL-STD 461 E. The testing of this device is discussed in a technical report EMI # B00-6 issued by AFRL/SNZW (8).

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT and subcomponents operated satisfactorily during all five phases of testing with the exception of the EEHS internal depth gauge. During Cold Operation Testing, the gauge began to flicker and subsequently lost all power. Due to failure of the internal depth gauge, it was eliminated as a subcomponent of the EEHS.

HYPOBARIC CONDITIONS

- 1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing. The EUT was able to maintain pressure without system failure up to 15,000 ft cabin altitude.
- 2. Rapid Decompression: The EUT operated satisfactorily following each rapid decompression event. The EUT functioned normally throughout this evaluation without any system degradation.

Note: Internal pressure was unchanged (< 0.05% during rapid decompression testing).

AIRBORNE PERFORMANCE

Flight qualified AFMED aeromedical crewmembers flying on C-130 and C-141 aeromedical evacuation missions conducted this phase of testing. Analysis of performance data indicated this unit was easy to enplane and deplane using four or more crewmembers. The EUT was positioned and secured to an aircraft floor using three 5,000 lbs., cargo tie-down straps and six "D" rings (see Appendix B). Then human factor characteristics were evaluated, e.g., securing methods, setup/tear down times and securing locations. The EUT should be positioned to allow visual monitoring of control systems throughout all phases of flight. The dive tank rack requires two cargo tie-down straps and four "D" rings for securing.

Feedback from other aeromedical evacuation crewmembers was obtained concerning EUT human factor considerations. The EUT was also form-fitted on an Army UH-60A Black Hawk helicopter. The EUT was positioned in the center of the helicopter in a forward/aft line position. It was noted that ten (10) special "D" rings that are compatible with the aircraft floor must accompany the Hyperlite unit if rotary airlift transport is anticipated.

EXPLOSIVE ATMOSPHERE

The EUT electronic subsystems (Mine Safety Appliances, Model 3000 Oxygen Monitor and David-Clark, Inc., Wired Headset System model 200, modified with Kit # WRC-HYBICS) were not evaluated for explosive atmosphere compliance with MIL-STD 810F (4). WRACC/TIECD engineers at Robins AFB, GA have not evaluated the EUT for explosive atmosphere testing. HQ AMC/SGXPL will coordinate future evaluation of this device for use onboard USAF tanker aircraft.

SUMMARY

AFMED found the SOS, Ltd., Hyperlite, Emergency Evacuation Hyperbaric Stretcher, Model 24/88/SAT/70 (S/N: 0000008994); Control Box Model Z08 (S/N: 005); David-Clark, Inc., Wired Headset System modified with kit # WRC-HYBICS; Amron International Diving Supply Inc., SCOTT® Pressur-Vak II Inhalator with Overboard Discharge, Model 803139-00 (P/N: 803152-02); Catalina S-80 (steel/80 cubic feet of air) dive tanks DOT number 3AL3000AS194479M4002 02A99 S80; Mine Safety Appliances, Model 3000 Oxygen Monitor; and patient comfort pad ACCEPTABLE for use during all phases of flight on all USAF aircraft (including fixed and rotary wing) with the exception of USAF Tanker aircraft. Explosive vapor testing of the David-Clark, Inc., Wired Headset System (modified with kit # WRC-HYBICS) and the Mine Safety Appliances, Model 3000 Oxygen Monitor was not performed. EUT approval onboard USAF Tanker aircraft will be granted upon successful testing of EUT electronic subcomponents requiring explosive vapor testing. The following comments and recommendations apply to the Hyperlite, Emergency Evacuation Hyperbaric Stretcher and its subsystems/components while in the aeromedical evacuation environment:

- a. Request a secondary method for securing oxygen tanks to the Hyperlite pressure chamber during manual carries.
- b. Due to the Hyperlite's size be aware of placement in all aeromedical aircraft to allow maximum observation of the patient and to prevent obstructing aircraft emergency exits.
- c. The Mine Safety Appliances, Co., Model 3000 Oxygen Monitor and the David-Clark, Inc., Wired Headset System, require 9-volt batteries for power. Operators must ensure adequate battery support to accomplish the mission.
- d. To aid ease in transporting a patient inside the Hyperlite, one additional carrying strap with two handles, placed at the mid-section must be included.
- e. Aircrew members and Hyperlite operators need to be vigilant in regard to pressure chamber safety, internal pressure monitoring, and compressed gas supply (air and oxygen) consumption. AFMED recommends descent and ascent absolute stops at 10, 15, and 20 FSW to assess patient comfort level and ability to clear ears. AFMED also recommends operation of Hyperlite only under the direct supervision of a healthcare provider with training in hyperbaric medicine.
- f. The Hyperlite Control Box, Model Z08 (S/N: 005) should be secured to the top of the chamber to allow visual monitoring of gauges in flight by operators. If unable to secure to chamber, an alternative position would be to mount directly to aircraft floor with cargo strap or web seats with a seatbelt.
- g. To secure chamber to aircraft floor, AFMED requires six "D" rings and three standard cargo tie-down straps running across the diameter (both ends and mid-section) and around the

ends in front of the Hyperlite end domes. See Appendix "B & C" for illustration of Hyperlite securing procedure.

- h. End dome cargo tie-down straps must be tightened in unison. Cargo strap ratchets must be on opposite sides of EEHS tube. End dome cargo tie-down straps should be snug over edges of EEHS but not too tightly winched down. Over tightening can cause tears to EEHS outer rubberized exterior, which would require repair post mission.
- i. AFMED recommends a padded mattress with pass-through straps to assist in loading the patient into the pressure chamber and aid in the patient's comfort. This mattress will isolate the patient from the affects of vibration conducted through the pressure chamber.
- j. AFMED recommends dive tanks be inspected/serviced by properly trained personnel (i.e. scuba shop) so that tanks are in compliance with Department of Transportation (DOT) guidelines and safety standards.
- k. Caution must be used when installing acrylic end domes. Manual traction must be maintained simultaneously on both domes until initial pressure seal is obtained. Lack of attention to this may cause dome to fall inward causing injury to patient. It may also cause excessive loss of pressurized gas.
- l. Routine briefing to patients should include special instructions on ear clearing to prevent barotrauma during descent. Few people have experience clearing ears while lying supine. Tipping the head backward with a small back/neck arching movement worked satisfactorily for test subjects. Special instructions must also include not holding breath or valsalving to prevent pneumo-barotrauma during ascent.
- m. Recommend patient comfort pad dimensions be increased to 176 inches by 24 inches. Thickness of pad must be increased by 50% to reduce vibration and thermal conduction during aeromedical evacuation. Recommend comfort pad have 6 hand-holds along sides to allow for patient movement. Recommend straps at both ends of pad to allow pad to be pulled through chamber to aid in patient positioning. Recommend patient securing straps be added to aid in transporting patient while on mattress alone.
- n. SOS Limited has proposed a secondary depth gauge to be used inside the EEHS during treatment dives. As of the publication of this technical report, a depth gauge has not been evaluated by AFMED. A mounting bracket to secure the proposed gauge to the inside of the foot- end dome needs to be designed and tested.
- o. Direct exposure to sunlight will cause inside temperature of EEHS to significantly increase. Frequent assessment of EEHS occupant must be done during extreme environmental exposure conditions.

- p. Some disassembly/configuration of the airframe internal cargo bay components (auxiliary fuel tank and ammo tray) may be necessary on the USAF UH-60 helicopter to accommodate the EUT.
- q. The Amron International Diving Supply Inc., SCOTT® Divers Inhalator Mask, Pressur-Vak II series, Model 803139 should be inspected and serviced per manufacturer's instructions.

REFERENCES

- 1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
- 2. Emergency Care Research Institute (ECRI)
- 3. MIL-STD 1472F, <u>Human Engineering Design Criteria for Military Systems, Equipment, and</u> Facilities
- 4. MIL-STD 810F, Environmental Test Methods and Engineering Guidelines
- 5. MIL-STD 461E, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference
- 6. Hyperlite Emergency Evacuation Hyperbaric Stretcher (EEHS) Manufacturer's Manual.
- 7. <u>AFMED Procedures Guide</u>, Internal Operating Instruction, Systems Research Branch, Air Force Research Laboratory
- 8. AFRL/SNZW Technical Report EMI # B00-6, "MIL-STD 461 EMI TEST REPORT MODEL 3400 INTERCOM SYSTEM"
- 9. SCOTT® Aviation, Inc., Operating and Maintenance Instructions, 803139 and 801238 Series Inhalators, July 1990, by AMRON INTERNATIONAL DIVING SUPPLY INC.
- 10. Operation and Installation Instructions, David-Clark, Inc., Wired Headset System model 200, modified with Kit # WRC-HYBICS

APPENDIX "A"

SPECIFICATIONS OF THE SOS, Ltd., HYPERLITE, EMERGENCY EVACUATION HYPERBARIC STRETCHER, MODEL 24/88/SAT/70

SPECIFICATIONS

General: Hyperlite Pressure Chamber

Size (Chamber):

88 in. Long. X 23.5 in. Diameter.

(Chamber thickness 0.15 in.)

Weight:

Pressure Chamber alone: 123 lbs

Complete EEHS setup: 300 lbs

Small Yellow Case empty: 23.02 lbs (10.44 kg) Small Yellow Case full: 100.70 lbs (45.68 kg) Large Yellow Case empty: 32.66 lbs (9.88 kg) Large Yellow Case full: 103.62lbs (47 kg)

Each O2 tank rack (with tanks): 94.60lbs (42.91kg).

Max. Burst Pressure: 265 psi

Working Pressure:

30.5 psi

Operating time:

Disposable Internal Depth Gauge: 15,000 hours.

Environmental

Operating Temperature: (-20°C to 40°C).

Storage Temperature: (-60°C to 180°C).

Hyperlite Pressure Chamber

Size (Chamber):

37.5 in. W. X 30.6 in. H. X 19.2 in. D.

Weight:

110 lbs.

Working Pressure:

30.5 psi

Operating time:

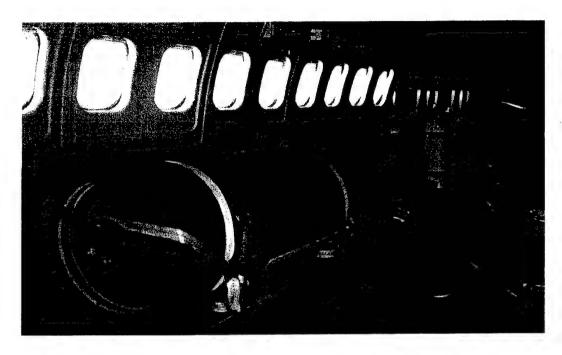
Disposable Internal Depth Gauge: 15,000 hours.

Environmental

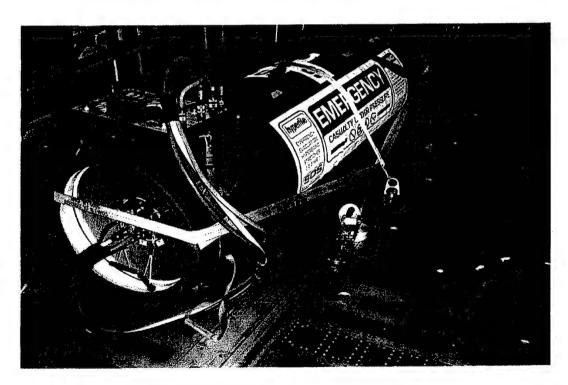
Operating Temperature: (-20°C to 40°C).

Storage Temperature: (-60°C to 180°C).

APPENDIX "B" Hyperlite Illustrations



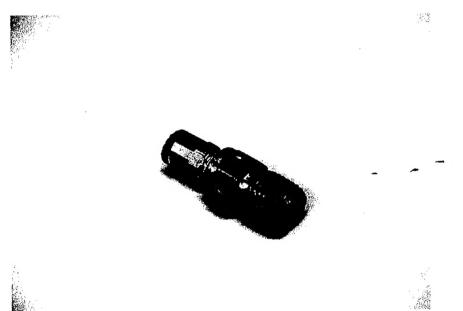
Hyperlite and dive tank rack aboard C-9A Nightingale



Hyperlite and dive tank rack aboard a C-141



Mine Safety Appliances, Co., Model 3000 provides oxygen monitoring capability inside the pressure chamber



Hexagonal brass air sampling fitting with holes

APPENDIX "C" Air Transportability Certification

File Code: 99.05.28

HEADQU

DEPARTMENT OF THE AIR FORCE

HEADQUARTERS AERONAUTICAL SYSTEMS CENTER (AFMC) WRIGHT-PATTERSON AIR FORCE BASE, OHIO

22 Feb 2000

MEMORANDUM FOR AFRL/HEPR

Chief, AFMEDL 2504 Gillingham Drive, Suite 25 Brooks AFB, TX 785235-5104

FROM: ASC/ENFC Bld 560

2530 Loop Road West

Wright-Patterson AFB OH 45433-7101

SUBJECT: Air Transportability Certification of Emergency Evacuation Hyperbaric Stretcher (EEHS) (your ltr, 26May99)

- The Emergency Evacuation Hyperbaric Stretcher (EEHS) system consists of the EEHS (89-in L x 24-in dia, -up to 500 lbs with patient), treatment equipment "Case 1" (26-inx26-inx24-in, up to 152-lbs), treatment equipment "Case 2" (25-inx25-inx12-in, up to 92-lbs) and dive tank racks (34-inx18-inx9-in, up to 105-lbs each). The EEHS system is approved for air transport and operating with patient on the C-5, C-9, C-130, C-141, C-17, and KC-135 aircraft.
 - a. The EEHS is pressurized and sealed when carrying a patient. The patient shall be aligned so that the feet are pointing forward. Place a cover under the EEHS to protect the unit from contaminants from the aircraft floor.
 - b. The units shall be restrained as shown in attachment 1. Forward/aft/lateral restraint strap shall be looped around the rim of the end covers but not on any other part of the EEHS. Route the strap across the face of the end cover but avoid contacting any hoses and connections. The recommend tiedown method is similar to tying down the water jug. Add a strap across the top of the EEHS for supplemental vertical restraint.
 - c. The treatment equipment cases and dive tank racks shall be strapped separately to the aircraft floor.
 - d. If the system is being used by a patient, all items including the EEHS shall be restrained to 9 G forward, 1.5G lateral and aft, and 2G vertical (up). Otherwise, the items shall be restrained as standard cargo.
- 2. All hazardous materials must be prepared and certified in accordance with the provisions of AFJMAN 24-204. This air transport certification is not to be considered as approval for hazardous materials. This approval is granted separately. Your servicing air terminal personnel can assist you in this regard. The vehicle shall be capable of withstanding the aircraft rapid decompression of up to 8.3 psi within 1/2 second without imposing any hazard to the aircrew or passengers.
- 3. A copy of this certification must accompany the item each time it is transported.
- 4. The air transportability engineer for this project is the undersigned. I can be reached at DSN 785-6039 or (937) 255-6039. My E-mail address is mark.kuntavanish@wpafb.af.mil. Please refer to project file code 99.05.28.

MARK A. KUNTAVANISH Aerial Delivery Group Crew Systems Branch

1 Atch: EEHS Tiedown cc: HQ AMC/DOV/DOKJ MTMCTEA/MTTE-DPE

